

REMARKS/ARGUMENTS

With entry of this amendment, claims 1-28, 48, and 49 are pending in the above-identified application. Claims 14-28 were previously withdrawn by the Examiner as being drawn to a non-elected invention. With this amendment, claim 1 is amended and claims 48 and 49 are added as set forth in detail below. Support for these amendments are identified in the following remarks. No new matter is added by these amendments. Examination and reconsideration of all pending claims are respectfully requested.

Claim rejections under 35 U.S.C. § 112

Claims 1-13 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. These rejections are addressed as set forth below.

"Highly acidic cleavage conditions"

First, the Examiner contends that the phrase "highly acidic cleavage conditions" renders the claims indefinite, the Examiner stating that it is "unclear what parameters and/or conditions" are encompassed by the phrase. Applicants respectfully traverse.

According to the MPEP, relative terminology does not render a claim indefinite where one of ordinary skill in the art would understand what is claimed in light of the specification. *See* MPEP § 2173.05(b). Thus, when a term of degree is presented in a claim, the initial inquiry is whether the specification provides some standard for measuring that degree. Further, even if a standard is not provided, the claim is definite if one of ordinary skill in the art, in view of the prior art and status of the art, would nevertheless be reasonably apprised of the scope of the invention. *See id.*

In the present case, the term "highly acidic cleavage conditions" is definite in view of the specification's disclosure and the knowledge and skill in the art as of the effective filing date. First, the specification provides a standard for the meaning of "highly acidic

cleavage conditions." The specification describes the state of the art with respect to cleavage of peptides from a resin support as part of the peptide synthetic process. In particular, the specification states as follows:

During the synthetic process side chains of certain amino acids comprising the growing chain are protected, blocked by a variety of chemical groups which remain until the completed peptide is removed from the insoluble resin support, usually by reaction with concentrated hydrofluoric or trifluoroacetic acid. During cleavage the majority of the protective groups are removed

(Specification at page 2, lines 22-29.) In setting forth the presently claimed invention in view of this state of the art, the specification goes on to describe peptides of the invention as comprising a chemically reversible protection means "resistant to the highly acidic cleavage conditions," substituted for the commonly used S-benzyl blocking of cysteine thiol groups. (*Id.* at page 4, lines 22-27.)

In view of the specification's disclosure as summarized above, the skilled artisan, reading the claims in light of the specification, would reasonably understand the term "highly acidic cleavage conditions" to mean acidic conditions used in cleavage of a synthesized peptide from a solid resin support, such conditions being sufficient to remove S-benzyl blocking of cysteine thiol groups, if present. Accordingly, Applicants submit that the term "highly acidic cleavage conditions" is definite under 35 U.S.C. § 112, second paragraph.

While Applicants believe the term "highly acidic cleavage conditions" to be definite as set forth above, but in order to further expedite prosecution of the instant application, claim 1 has been amended to recite "highly acidic cleavage conditions used for peptide cleavage from the solid support." Support for this amendment is found in the application as filed as noted above (e.g., at page 2, lines 22-29; and page 4, lines 22-27). Thus, claim 1 as amended explicitly recites a standard for the meaning of "highly acidic cleavage conditions." For reasons discussed above, Applicants believe this amendment to be commensurate with the meaning of claim 1 as would be understood by the skilled artisan reading the claim in light of the

specification. Therefore, it is believed that this amendment does not change or narrow the meaning of the claims.

In view of the foregoing remarks and amendment, withdrawal of the rejection is respectfully requested.

"Suitable for use in an immunological assay"

The Examiner characterizes the phrase "suitable for use in an immunological assay" as an intended use, and further contends that it is "unclear how the intended use ... sets apart the solid phase recited in the claims and those in the art."

While Applicants disagree with this aspect of the rejection, but in order to further expedite prosecution of this application, Applicants have deleted the phrase "suitable for use in an immunological assay." In view of this amendment, the present rejection is obviated. Withdrawal of the rejection is respectfully requested.

Recitation of Applicants' interpretation of the claims

The Examiner states that Applicant is "required to amend the claims to clearly reflect" an "interpretation" of the claims noted in Applicants' previous response, in particular, that the recited peptide is in a form following synthesis, cleavage of the peptide from a solid support, and subsequent immobilization onto a solid phase. Applicants respectfully disagree with the Examiner's interpretation of 35 U.S.C. § 112, second paragraph, as requiring this amendment.

There are two requirements under § 112, second paragraph. *See* MPEP § 2171. One is that the claims "set forth the subject matter that applicants regard as their invention." The other is that the claims must particularly point out and distinctly define the metes and bounds of the subject matter to be protected. *Id.* While the Examiner has not stated clearly which requirement is being relied upon in setting forth the present rejection, the Examiner appears to

rely on the first requirement. It is under this assumption that Applicants will address the Examiner's remarks.

As stated by the MPEP, the requirement that the claims "set forth the subject matter that applicants regard as their invention" is a subjective one because it is dependent on the views of the applicant. (*See* MPEP § 2171.) Therefore, a rejection based on an alleged failure to satisfy this requirement is appropriate only where the applicant has stated, somewhere other than in the application as filed, "that the invention is something different from what is defined by the claims." (MPEP § 2171.) In the present case, Applicants have not stated that their invention is different from that recited in the claims. It is noted that Applicants' remarks, in the Amendment dated 9/21/2005 (page 10), were in the context of distinguishing the claims as previously amended from Cosand *et al.* Thus, there is no indication of a subjective belief that the invention is different from the claims as previously amended.

While Applicants disagree with the present rejection and reasons for rejection, but in order to further expedite prosecution of the instant application, Applicants have amended claim 1 to recite "an isolated peptide, wherein said peptide is immobilized on a solid phase following synthesis of the peptide on a synthesis solid support and cleavage of the peptide therefrom." Support for this amendment is found in the application as filed at, for example, page 9, line 27, to page 10, line 34; as well as Examples I-III. In view of this amendment and the remarks set forth above, withdrawal of the present rejection is respectfully requested.

Claim rejections under 35 U.S.C. § 103

Claims 1-13 currently stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Cosand *et al.*, either alone (claims 10, 11, and 13), or in combination with either Brugger *et al.* (claims 1-4 and 6-9) or Neurath *et al.* (claims 5 and 13).

While not agreeing with these rejections for at least the reasons of record, Applicants' believe these rejections to be obviated in view of the present amendments to

independent claim 1. Claim 1 now recites, *inter alia*, "an isolated peptide, wherein said peptide is immobilized on a solid phase suitable for use in an immunological assay following synthesis of the peptide on a synthesis solid support and cleavage of the peptide therefrom," wherein the sequence of the peptide "comprises two Cys residues which are separated from each other by at least two but fewer than twenty non-Cys amino acid residues and wherein thiol groups of the Cys residues are reversibly protected from oxidation by a chemically reversible means resistant to highly acidic cleavage conditions." None of the cited references teach or suggest a peptide as presently claimed. In particular, it is noted that the only discussion in the cited references, with respect to protection of Cys thiol groups, is in the context of protection during synthesis of the peptide on a resin support. (See, e.g., Cosand *et al.* at column 9, line 54, to column 10, line 27; Brugger *et al.* column 3, lines 15-22; Neurath *et al.* at column 33, line 20, to column 34 line 40.)

For the reasons above, Applicants believe the present claims to be patentable under 35 U.S.C. § 103 over Cosand *et al.*, whether alone or in combination with Brugger *et al.* or Neurath *et al.* Withdrawal of the rejections is respectfully requested.

Other Claim Amendments

New dependent claims 48 and 49 have been added to more fully claim certain embodiments of the present invention.

Claims 48 recites the composition of claim 1, "wherein the highly acidic cleavage conditions comprise hydrofluoric acid (HF) or trifluoroacetic acid (TFA)." Support for this amendment is found in the application as filed at, for example, page 2, lines 22-28 (referring to standard techniques for peptide synthesis as including cleavage by, *e.g.*, hydrofluoric or trifluoroacetic acid); page 9, lines 30-36 (referring, in the context of the present invention, to selection of chemically reversible protection means for resistance to "the high concentrations of acid used to cleave the peptide from the resin solid phase"); and Example I, page 20, lines 20-23 (describing a specific example of synthesis of a peptide of the present invention and its cleavage from a resin support using standard HF procedures).

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Application No. 09/733,239
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1648

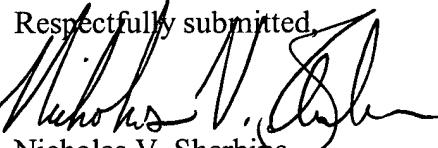
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Claim 49 recites the compositions of claim 1, "wherein the solid phase is selected from the group consisting of a microtiter plate, a glass bead; a latex bead entrapped on a microporous membrane; a tube; a filter; and a chromatographic surface." Support for this claim is found in the application as filed at, for example, page 16, lines 32-36; and page 27, line 34, to page 28, line 7.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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